insoluble overlayer on the second surface of the doped electro-active polymer layer, the doped electro-active polymer layer comprising an electro-active polymer doped with an ionic exchangeable releasable dopant and the overlayer being substantially impermeable to said dopant.

REMARKS

Claims 1-6, 25-30, and 44-58 are presently pending. Claims 7-24 and 31-43 were previously withdrawn from consideration. Claims 4 and 48 are presently amended.

SPECIFICATION

The Office alleges that the previous amendments to claims 4 and 48 to recite sulfonated polytetrafluoroethylene in lieu of "Nafion" constitute new matter. The Office requires that Applicant submit documentation to support the amendment.

Claims 4 and 48 have been amended to delete sulfonated polytetrafluoroethylene and to replace said term with "perfluorosulfonic acid/PTFE (polytetrafluoroethylene) copolymer". Perfluorosulfonic acid/PTFE copolymer more specifically identifies Nafion than sulfonated polytetrafluoroethylene. Applicant submits herewith documentation (in an IDS[1]) that supports this amendment. Applicant respectfully requests favorable reconsideration and withdrawal of this rejection of claims 4 and 48 under 35 U.S.C. § 132.

35 U.S.C. § 102

Claims 1-3, 25, 27-30, 44-47, and 51-58 stand rejected as being allegedly anticipated by Reynolds *et al.* The Office alleges that "Reynolds *et al.* teaches a bilayer coating for an

[1] The document is submitted as part of Applicant's Reply to the Office Action. In accordance with MPEP § 609(III)(C)(3), Applicant need not satisfy the requirements of 37 C.F.R. 1.97 and 1.98 in order to have the Examiner consider the information contained therein.

electrode wherein the first layer contacts the electrode and is loaded with drug, and the overlayer inhibits the release of the drug."

Applicant respectfully traverses this rejection under 35 U.S.C. § 102. The Court of Appeals for the Federal Circuit has espoused the long settled law concerning anticipation under 35 U.S.C. § 102: anticipation can only be established by a single prior art reference which discloses each and every element of the claimed invention. Dayco Products, Inc. v. Total Containment, Inc., 66 U.S.P.Q.2d 1801, 1809 (Fed. Cir. 2003). Reynolds does not teach each and every element of the claimed invention. Although Reynolds teaches a bilayer coating for an electrode, it does not teach that the overlayer inhibits the release of the drug. Specifically, Reynolds states that "studies of bilayers, consisting of low redox potential conducting polymer inner films (*e.g.*, PP/PSS) and high redox potential electroactive polymer outer films (*e.g.* PNMP-Cl, poly(vinylferrocene), have shown that the redox switching and ion transport of the inner films *are not hampered by the presence of the outer films*...." (Emphasis added)(p. 128, col. 2 to p. 129, col. 1). Unlike Reynolds' outer films (*e.g.* PNMP-Cl and poly(vinylferrocene)), the overlayer polymer of the present invention, such as poly(vinyl butyrl), poly(vinyl acetate), and nafion, are not redox or electroactive polymers. According to the present claims, the bi-layer coating comprises a doped electro-active polymer layer on the electrode and a water-insoluble overlayer on the doped electro-active polymer layer. The electro-active polymer of the doped electro-active polymer layer is doped with an ionic exchangeable releasable dopant and the overlayer is substantially impermeable to the dopant. The outer films in Reynolds do not and were not intended to hamper ion transport. In contrast, the overlayers of the present invention are non-redox inactive polymers that prevent spontaneous ion exchange. Accordingly, Reynolds

does not anticipate the claimed invention. Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 102.

35 U.S.C. §103

Claims 1, 4, and 48-50 stand rejected under 35 U.S.C. § 103 as being allegedly unpatentable over Vachon *et al.* in view of Reynolds. The Office alleges that "Vachon *et al.* teaches an implantable electrode having a polymer coating loaded with a drug wherein the coating may contain Nafion or polypyrrole, but fails to teach more than one layer covering the electrode." According to the Office, Reynolds provides this missing element.

Applicant respectfully traverses this rejection under 35 U.S.C. § 103. To establish a *prima facie* case of obviousness, there must be 1) a suggestion to combine or modify, 2) a reasonable expectation of success and 3) the references must suggest all of the claim limitations. MPEP § 2143. As the Office concedes, Vachon does not teach a bilayered CDD. Reynolds does not cure this defect in Vachon. As Applicant asserts above, Reynolds does not teach Applicant's invention. Reynolds merely teaches an electrode with two layers of electroactive polymers. Reynolds does not teach or suggest a bilayer system of the present invention, which comprises an electroactive inner layer and inactive overlayer. The purpose of the overlayer is to prevent spontaneous release of the drug. The overlayer stops or limits this ion exchange process. (Spec., para. 42). The coating disclosed in the Vachon *et al.* patent releases the dopant due to spontaneous release caused by an ion exchange with the surrounding environment. The Vachon coating does not provide any method for controlling that release after implantation. As discussed above, Reynolds' outer films are electroactive and do not prevent ion exchange. Accordingly,

Applicant submits that Vachon in view of Reynolds do not render the present invention obvious. Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claims 1, 25, 26, and 27 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Phipps *et al.* in view of Reynolds *et al.* Specifically, the Office alleges that "Phipps *et al.* teaches an electrotransport device placed on the patient's skin comprising an electrode and a hydrophobic ion exchange material, but fails to teach a bilayer coating on the electrode." Reynolds allegedly cures this defect.

Applicant respectfully traverses this rejection. As the Office concedes, Phipps does not teach a bilayer electrode. However, Reynolds does not cure this defect. Although Reynolds teaches a bilayer electrodes, it does not teach the bilayer electrode of the present invention. Reynolds teaches a bilayer of electroactive inner and outer layers. The poly(N-methyl pyrrole) and poly(vinyl ferrocene), the outer films taught in Reynolds, are redox electroactive polymers. A person of ordinary skill in the art would not be motivated to combine Phipps and Reynolds to reach the present invention. Phipps does not teach a bilayer CDD, and Reynolds does not provide a bilayer electrode in which the outer layer is "substantially impermeable to said dopant". Accordingly, Phipps in view of Reynolds do not render the claimed invention obvious. Applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. § 103.

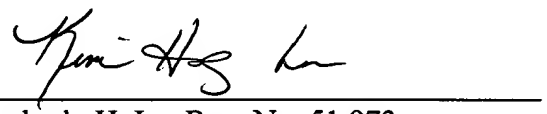
CONCLUSION

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant, therefore, respectfully requests that the Office reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete

response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance. If the Office believes, for any reason, that personal communication will expedite prosecution of this application, he is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

Respectfully submitted,



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